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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,667	01/14/2004	Anthony John Kinney	BB1071 US DIV2	7292
23906 7590 02/26/2008 E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1122B 4417 LANCASTER PIKE WILMINGTON, DE 19805			EXAMINER KUMAR, VINOD	
			ART UNIT 1638	PAPER NUMBER
			NOTIFICATION DATE 02/26/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

## Office Action Summary

**Application No.**

10/757,667

**Applicant(s)**

KINNEY ET AL.

**Examiner**

Vinod Kumar

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/24/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>SAME</u> .                               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                          |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 7, 2007 has been entered. Applicant's declaration filed under 37 CFR § 1.132 in the paper of December 7, 2007 is also entered.

***Status of objections and rejections***

2. Claims 22-24 are pending.
3. Claims 1-21 are canceled.
4. Claims 22-24 are examined on merits in the instant Office action.
5. Objection to the specification is withdrawn in light of persuasive arguments filed in the paper of December 7, 2007.
6. Objections to claim 24 has been withdrawn in light of claim amendment filed in the paper of December 7, 2007.
7. Rejection of claims 22-24 under nonstatutory obviousness-type double patenting is withdrawn in light of persuasive arguments filed in the paper of December 7, 2007.
8. Rejection of claim 24 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is withdrawn in light of claim amendment filed in the paper of December 7, 2007.

9. Rejection of claim 24 under 35 U.S.C. 112, 1<sup>st</sup> paragraph is withdrawn in light of claim amendment filed in the paper of December 7, 2007.

***Claim Rejections - 35 USC § 112***

10. Claims 22-23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a food prepared from soybean seeds having reduced quantity of glycinin and/or  $\beta$ -conglycinin, wherein said seeds are prepared by a method comprising antisense or sense suppression of endogenous seed glycinin and/or  $\beta$ -conglycinin gene expression, comprising transformation of soybean seeds with a chimeric gene which comprises a nucleic acid fragment derived from soybean glycinin or  $\beta$ -conglycinin coding sequence, does not reasonably provide enablement for reducing the levels of *any* soybean seed storage protein, comprising transformation of soybean seed with a chimeric gene which comprises a nucleic acid fragment encoding all or a portion of a soybean glycinin or beta-conglycinin seed storage protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record stated in the Office action mailed on September 21, 2007. Applicant traverses the rejection in the paper filed on December 7, 2007.

Applicant argues that examples 1-3 of the specification provide enough guidance to one skilled in the art to reduce expression of the conglycinin seed storage proteins in a transgenic soybean seed using antisense or sense suppression based gene silencing approaches. Applicant also argues that example 4 provides guidance in suppressing expression of glycinins in soybean seeds using similar approaches. Applicant further

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argues that the desired gene suppression can be achieved whether or not a full-length sequence is used or whether or not there is some sequence variation. Applicant cites Table 1 (pages 19-20), page 20 at lines 10-17, and page 24 at lines 14-20 of the specification to support the arguments. Applicant further argues that Fader's declaration filed under 37 CFR § 1.132 filed in the paper of December 7, 2007, shows that all the glycinin were suppressed when truncated forms of the G1 and G4 subunits were expressed in sense orientation (response, pg 7, lines 1-23).

Applicant's arguments were fully considered but were deemed to be unpersuasive.

It is maintained that example 1 of the specification clearly suggests unpredictability of reducing expression of endogenous seed storage proteins in a plant seed cell using sense suppression based gene silencing approach.

It is further maintained that Table 1 clearly suggests the following: (a) majority of transgenic embryos failed to exhibit reduced levels of all conglycinin subunits, and (b) expression of an unrelated gene delta-12 desaturase in one transgenic embryo. These unpredictable results further conform with the teachings of Bruening (1996) which clearly suggests that the occurrence of gene silencing by sense suppression may be the unexpected outcome, and such transgenic lines may not hold to character when propagated by seed.

It is further maintained that examples 2 and 3 of the specification do not suggest that promoter region of  $\beta$ -conglycinin was capable of suppressing expression of one or more class of non-conglycinin soybean seed storage proteins, or at least two non-

conglycinin soybean seed storage protein genes as encompassed by the breadth of claims 22 and 23, respectively.

It is further maintained that while example 4 of the specification provides guidance on making cosuppression constructs containing the cDNAs corresponding to the group I cDNA of Glycinin and the group II cDNA of Glycinin linked each in sense direction to the  $\beta$ -conglycinin promoter, however, example 4 fails to address the core issue of reducing the expression levels of glycinin,  $\beta$ -conglycinin and other seed storage proteins in a soybean seed by transforming said seed with a construct comprising an antisense or sense sequence of glycinin or  $\beta$ -conglycinin. It is further maintained that no transgenic embryos with reduced levels of soybean seed storage proteins were produced in example 4.

As discussed in the previous Office actions, antisense suppression of gene expression is highly unpredictable (see page 12, 1<sup>st</sup> paragraph of Office action mailed on 01/10/2007). The teachings of Elomma et al. or Colliver et al. clearly suggest that success of gene suppression of a target gene depends on the % identity between the sequence of the antisense construct and the target gene sequence. In view of significant sequence differences between different soybean seed storage proteins (target genes) and the promoter region of  $\beta$ -conglycinin, the promoter region (transcribed part) of  $\beta$ -conglycinin would be unable to down-regulate gene expression of any seed-storage protein.

In the absence of guidance and unpredictability of the related art as discussed above, it is maintained that undue experimentation would have been required by a

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skilled artisan at the time the claimed invention was made to determine how to use antisense or sense cosuppression based gene silencing approaches in reducing the levels of any soybean seed storage protein using a nucleic acid fragment encoding all or a portion of glycinin or beta-conglycinin. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, it is maintained that undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to make and use the claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

11. Claims 22-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed on September 21, 2007.

In the response filed on December 7, 2007, Applicant states that claim amendment and Fader's declaration (37 CFR § 1.132) filed in the paper of December 7, 2007 should overcome written description rejection (response, paragraph bridging pages 7 and 8).

It is noted that Applicant did not present any arguments against the rejection. Accordingly, it is maintained that there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. Accordingly, the rejection is maintained.

***Claim Rejections - 35 USC § 102 & 103***

12. Claims 22-24 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trueblood et al. (US Patent No. 4,267,118, issued on May 12, 1981) for the reasons of record stated in the Office action mailed on September 21, 2007. Applicant traverses the rejection in the paper filed on September 21, 2007.

Applicant argues that page 2, lines 22-24 of the instant specification describes that the food which constitutes the subject matter of the instant invention is directed to protein concentrates, isolates, and textured protein products, not soybean oil obtained from seeds containing reduced levels of soybean seed storage proteins. Applicant further argues that the amended claims replace food with soy protein, and thus obviate prior art rejection (response, page 8, lines 21-25).

Applicant's arguments were fully considered but were deemed to be unpersuasive.

It is maintained that the instantly claimed invention reads on soybean oil which inherently comprises oilbody proteins (e.g. oleosin, a soy protein).



In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., food which constitutes protein concentrates, isolates, and textured protein products derived from soybean seeds which is transformed with a suppression construct to down-regulate endogenous seed storage proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is maintained that the instantly claimed food has the same structural limitations as that taught by the reference. Soybean oil as a food obtained from the claimed method appears to be identical to the soybean oil of the prior art which inherently comprises oleosins (same as soy protein). See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Accordingly, the rejection is maintained.

13. Claims 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Staswick et al. (Archives of Biochemistry and Biophysics, 223:1-8, 1983)

Staswick et al. disclose soybean seeds having reduced levels of glycinin. The soybean seed storage proteins with reduced levels of glycinin would inherently constitute food. See in particular, page 1, abstract, introduction; page 2; left column. The soybean seed storage proteins with reduced glycinin levels disclosed in the reference was not made using the same method as the instantly claimed food. However, the instantly claimed food has the same structural limitations as that taught by the reference. Soybean seed storage proteins with reduced glycinin levels as a food obtained from the claimed method appears to be identical to the soybean seed storage proteins with reduced glycinin levels of the prior art. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

### ***Conclusions***

14. Claims 22-24 are rejected.

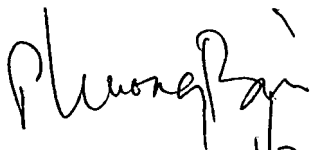
### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
PHUONG T. BUI  
PRIMARY EXAMINER  
1/29/08